DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

September 20, 2000

Ref: 2000-DAL-WL- 16

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Harold J. Lees
President and CEO
MCMI Food Company
The Ashford Building
8122 Datapoint, Ste. #900
San Antonio, Texas 78229

Dear Mr. Lees:

We inspected your seafood firm, Seafood Wholesalers, Inc., 4746 Dodge St., San Antonio, Texas, on August 1, 2 and 4, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123. These deviations, some of which were previously brought to your attention, cause your seafood products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

Our inspection revealed your processing of seafood deviates from the regulations contained in 21 CFR Part 123 as follows:

- You must have written HACCP plans to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6 (b). However, your firm does not have HACCP plans for fresh, refrigerated vacuum packed mahi mahi and fresh, ready-to-eat picked Blue Crab products.

- You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6 (c) (1). However, your firm's HACCP plan for scombrotoxin forming species of fish does not include storing and staging as critical control points for controlling the food safety hazards.

- You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6 (b), however, your firm did not record temperature monitoring observations for the critical control points at storing and staging for scombroid fish species.

- You must maintain verification records for the receiving and storing critical control points identified in your HACCP plan to comply with 21 CFR 123.8 (a). However, your firm is not calibrating the thermometers used for temperature checks during the receiving and storage of scombroid fish species.

- You must maintain sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11 (c). However, your firm had no sanitation monitoring records or procedures in all eight areas of sanitation.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. At the conclusion of the inspection your firm was issued a Form FDA-483 which is a list of the Investigators' observations of deviations noted during the inspection. (attached) It is your responsibility to ensure adherence to each requirement of the Act and regulations. Your firm has been advised that a sample of amberjack collected during this inspection was decomposed and during the inspection the investigator observed red snapper that was borderline in quality and voluntarily destroyed by your firm.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to seizure, and/or obtaining a court injunction against further marketing of your seafood products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your corrections. Your reply should be sent to Gwendolyn Sue Gilbreath, Compliance Officer, at the above address.

Sincerely,

Michael A. Chappell
Dallas District Director

attachment

cc: Mr. Peter Gryska, General Manager
Seafood Wholesalers, Inc.
1201 Weiss St.
Houston, Texas 77009

Mr. Roger Pena, Facility Manager
Seafood Wholesalers, Inc.
4746 Dodge St.
San Antonio, Texas 78217